

### **Remarks**

Initially, Applicants wish to thank Examiner Ware and her supervisor David Naff for extending the courtesy of a telephone interview on March 9, 2005. During the interview the outstanding §112 rejection, as well as, the cited references with regard to both the §102 and §103 rejections were discussed. Applicants believe the below comments are in accordance with those discussions.

Claims 54 and 95 have been amended in accordance with the discussions during the telephone interview. Please cancel claims 76-94 without prejudice or disclaimer to the subject matter therein. Following this amendment claims 54, 57-61 and 63-107 will be pending. Support for the claims as amended may be found for instance, with regard to the hydrophilic and hydrophobic amino acids on page 2, lines 2-9, page 3, lines 26-30, page 4, lines 16-18, page 6, lines 12-16, original claims 13 and 14, the examples and throughout the application as originally filed; support of non-covalently linked may be found for instance in claim 28 as originally filed and throughout the specification and examples; support of oral administration may be found for instance on page 8, lines 2-4, page 10, lines 3-5, and throughout the examples and application as originally filed. No new matter is added as a result of this amendment.

Applicants have also concurrently filed a supplemental Information Disclosure Statement. The references cited in the Information Disclosure Statement were cited in the parent case which was before Examiner Ware, but according to Applicants' records have not been submitted in the present case.

Applicants believe the currently amended claims and remarks below address the Examiner's remaining concerns.

### **Rejection Under 35 U.S.C. § 112 ¶2**

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 54, 57-61, 63-75 and 95-107 were rejected as being indefinite for recitation of the phrase “‘non-covalently protected’ because it is unclear what this is intended to mean in the claims per se.” Applicants have amended the claim language to recite the phrase “linked” to instead of “protected” to better clarify the non-covalent “attachment” of the drug within the internalized domain or pocket as discussed during the interview.

The rejection is respectfully obviated.

**35 U.S.C. §102(b)**

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in a public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 54, 57-61, 63-75 and 95-107 were rejected under 35 U.S.C. §102(b) as anticipated by Peterson et al. (U.S. Patent 4,356,166). "Anticipation under 35 U.S.C. § 102 requires the disclosure in a single piece of prior art of each and every limitation of a claimed invention." (*Electro Med. Sys. S.A. v. Cooper Life Sciences*, 32 U.S.P.Q.2d 1017, 1019 (Fed. Cir. 1994)). The claim as amended is directed to a pharmaceutical composition comprising an active agent non-covalently linked in an internalized domain or pocket of an amino acid polymer wherein said amino acid polymer structure comprises at least one hydrophilic component and at least one hydrophobic component designed to promote the formation of said internalized domain or pocket; and said hydrophilic component and hydrophobic/non-polar component are selected to manipulate the tertiary structure of said amino acid polymer to control degradation and release of said active agent; wherein said hydrophilic component is lysine, arginine, asparagine, cysteine, glutamic acid or combinations thereof; wherein said hydrophobic/non-polar component is valine, tyrosine, proline, leucine, tryptophan, methionine, phenylalanine, glycine, isoleucine, benzyl glutamic acid, or combinations thereof; and wherein said pharmaceutical composition is in a form suitable for oral administration.

The Examiner stated that the "features upon which applicant relies (i.e. non-covalent attachment) are not recited in the rejected claim(s)" and therefore the claims were anticipated by Peterson et al. for the reasons of record. As discussed and clarified during the interview and as amended herein, the claims now recite that the active agent is "non-covalently linked". Peterson et al. is directed to covalent attachment of a bioactive, not non-covalently linked active agents. Further, Peterson et al. does not recite the importance of using the specific amino acids to make the polymer structures recited in the claims. Additionally, the claims now recite that the pharmaceutical composition is in a form suitable for oral administration. Peterson et al. is directed to implants. Therefore the claims as currently amended are not anticipated by Peterson

et al., for at least the above discussed limitations alone or in combination. The rejection over Peterson et al. is respectfully traversed.

**35 U.S.C. §103(a)**

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 54, 57-61, 63-75 and 95-107 were rejected under 35 U.S.C. 103(a) as obvious in view of Peterson et al. in view of Latham et al. ('227) and Kramer et al. Again, Applicants have amended the claim to recite the active agent is "non-covalently linked" as clarified above. Each reference cited by the Examiner is directed to covalent attachment of the active agent to an amino acid sequence. Further, as discussed above the references do not suggest the advantage of using the specifically recited amino acids in the claimed polymer structure for non-covalent linkage or protection. Therefore, one would not be motivated to use alone or in combination the references to arrive at the claimed invention.

Prior art references in combination do not make an invention obvious unless something in the prior references would suggest the advantage to be derived from combining their teachings. *In re Sernaker*, 217 U.S.P.Q. 1, 6 (Fed. Cir. 1983). There must be something in the prior art as a whole to suggest the desirability, and thus the obviousness, of making the combination. *Lindemann v. Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 221 U.S.P.Q. 481, 488 (Fed. Cir. 1984). *Interconnect Planning Corporation v. Feil, et al.*, 227 U.S.P.Q. 543, 551 (Fed. Cir. 1985). In the present case there is no such motivation. This is particularly true given the recitation in Applicant's claims to a composition where the active agents are non-covalently linked.

Each of the claims 55, 57-61, 63-94 and 96-107 are dependent claims on claims 54 and/or 95, and therefore incorporate all of the limitations of Claim 54 and 95 in addition to the further limitations set forth in the dependent claims at issue. As stated above, a proper *prima facie* obviousness rejection requires that the prior art reference(s) must teach or suggest all of the claim limitations. For the reasons set forth above, Peterson et al. in view of Latham et al. and

Kramer et al. does not render obvious the claims. As stated in the M.P.E.P., "[i]f an independent claim is nonobvious under 35 U.S.C. § 103, then any claim depending therefrom is nonobvious." See M.P.E.P. § 2143.03 (citing *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988)).

For all the reasons discussed above, Applicant's claims are patentable in view of the references of record. The rejection is respectfully traversed.

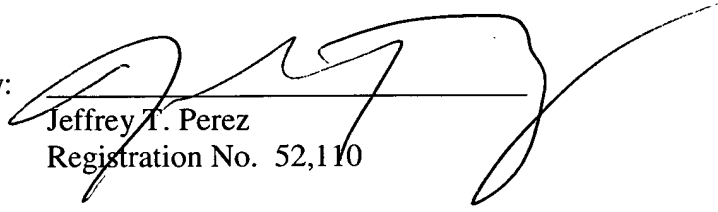
No additional fees are believed to be necessary in connection with the filing of this paper. However, in the event any fees are necessary, the Commissioner is hereby authorized to charge Deposit Account 50-0206 for any such fees.

Respectfully submitted,

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